

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE))
PRODUCTS LIABILITY LITIGATION) MDL NO. 1203

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8526

Bartle, C.J.

September 2, 2010

Cheryl K. Dawson ("Ms. Dawson" or "claimant") a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Leonard R. Dawson, Ms. Dawson's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In November, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Ted M. Parris, M.D., F.A.C.C. Based on an echocardiogram dated October 8, 2001, Dr. Parris attested in Part II of Ms. Dawson's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.⁴ Based on such findings,

3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Parris also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition,
(continued...)

claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$528,405.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, Rajesh K. Shroff, M.D., stated that claimant had "[m]oderate mitral regurgitation." Dr. Shroff, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA").

See Settlement Agreement § I.22.

In February, 2004, the Trust forwarded the claim for review by Jeffrey S. Todd, M.D., one of its auditing cardiologists. In audit, Dr. Todd concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Todd explained

4. (...continued)
however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

that "[t]he [mitral regurgitant] jet is clearly less than 20% of the [left atrial] area. The sonographer did not trace the [mitral regurgitant] jet or the [left atrial] dimensions, and thus provides no objective findings to support the claim of moderate [mitral regurgitation]."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Dawson's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted letters from Dr. Parris and Dr. Shroff. Dr. Parris stated that he performed a second review of claimant's echocardiogram and confirmed his diagnosis of moderate mitral regurgitation. Dr. Shroff stated that claimant's October 8, 2001 echocardiogram "was interpreted as showing moderate mitral regurgitation." Claimant also noted that Dr. Parris is a Board Certified cardiologist and Dr. Shroff participated in the Trust's Screening Program.⁷ According to

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Dawson's claim.

7. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

claimant, there is a reasonable medical basis for her claim because these two cardiologists reached the same determination.

The Trust then issued a final post-audit determination, again denying Ms. Dawson's claim. Claimant disputed this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Dawson's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5239 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 10, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Dawson reasserts the arguments that she made in contest; namely, that her attesting physician's finding has a reasonable medical basis because two qualified cardiologists independently agreed on the existence of moderate mitral regurgitation and because Dr. Shroff participated in the Trust's Screening Program. Additionally, claimant contends that the auditing cardiologist has no authority to base his finding on a difference of opinion or on the sonographer's failure to make tracings on the echocardiogram. Claimant also

notes that the auditing cardiologist did not provide "his own opinion as to the percentage of the [mitral regurgitant] jet."

In response, the Trust argues that claimant cannot meet her burden of proof by simply having more doctors attest that she had moderate mitral regurgitation. The Trust also asserts that the auditing cardiologist did not base his findings simply on a difference of opinion with the attesting physician or on the sonographer's lack of tracings; rather, he found that the attesting physician's diagnosis with regard to the level of mitral regurgitation lacked a reasonable medical basis. The Trust further argues that the auditing cardiologist is not required to provide measurements of the mitral regurgitant jet and instead is permitted to eyeball the regurgitant jet to assess the severity. Finally, the Trust contends that Dr. Shroff's participation in the Screening Program for Fund A benefits does not entitle his opinion to any greater deference.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Abramson determined that:

In reviewing the transthoracic echocardiogram from 10/08/01, my visual estimate is that there is only trace to mild mitral regurgitation. No [mitral regurgitation] was evident in the parasternal long axis view. I measured the mitral regurgitant jet and the left atrial area in the same frame in five representative cardiac cycles. My measurements for mitral regurgitant jet

area/left atrial area are $0.4 \text{ cm}^2/24.6 \text{ cm}^2$, $0.3 \text{ cm}^2/26.7 \text{ cm}^2$, $0.3 \text{ cm}^2/23.5 \text{ cm}^2$, $0.4 \text{ cm}^2/25.1 \text{ cm}^2$, $0.5 \text{ cm}^2/24.9 \text{ cm}^2$. These ratios are 2%, 1%, 1%, 2%, and 2%, all of which are considerably less than 20% which is consistent with trace to mild mitral regurgitation.

In response to the Technical Advisor Report, claimant argues that Dr. Abramson's visual inspection and measurements do "not negate the visual inspection of two other qualified cardiologists." Claimant also argues that she should not be penalized because the sonographer failed to trace the mitral regurgitant jet and the left atrial area on the tape.

After reviewing the entire show cause record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately contest the specific findings of the auditing cardiologist or the Technical Advisor. Dr. Todd specifically observed that "[t]he [mitral regurgitant] jet is clearly less than 20% of the [left atrial] area." In addition, Dr. Abramson, although not required to do so, provided specific measurements from her review of claimant's echocardiogram and concluded that "all of [the measurements] are considerably less than 20%." In support of her claim, Ms. Dawson relies only on the conclusory letters from Dr. Parris and Dr. Shroff, neither of whom adequately refutes or responds to the specific findings of Dr. Todd and Dr. Abramson. On this basis alone, claimant has failed to meet her burden in proving that there is a reasonable medical basis for her claim.

We also reject claimant's assertion that she is entitled to Matrix Benefits because Dr. Shroff, who participated in the Trust's Screening Program, determined her echocardiogram demonstrated moderate mitral regurgitation. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive for an echocardiogram performed in the Screening Program is a limited amount of medical services or cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims

for Matrix Benefits. See PTO No. 2662 at 13 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, or that a cardiologist's participation in the Screening Program entitles his or her opinion to more weight, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Dawson's claim for Matrix Benefits and the related derivative claim submitted by her spouse.